

Declaration and Supplemental Reply were submitted prior to the deadline of the prosecution suspension request, January 13, 2003, she would consider them and issue a new Official Action resetting the period for response. Accordingly, Applicants request consideration of the present Supplemental Reply and the accompanying Declaration of Max Rombi Pursuant to 37 C.F.R. § 1.132. If, upon consideration of these materials, the Examiner should believe that the presently claimed invention is not in condition for allowance, Applicants respectfully urge that a new, non-final Official Action be issued.

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 3, 25, and 26 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yasuda et al. (*J. Jpn. Soc. Food Sci. Technol.* 38(12):1098-1102 (1991)). The Examiner argues that Yasuda et al. disclose a composition for decreasing halitosis containing an 80% alcoholic extract of green tea. The Examiner further suggests, albeit erroneously, that Applicants disclosed that an 80% alcohol green tea extract inherently contains 20-30% catechols and 5-10% caffeine. Thus, the Examiner concludes that the presently claimed invention and the extract of Yasuda et al. must be the same because allegedly the same plant material was extracted. This rejection is respectfully traversed.

Initially, Applicants respectfully point out that "green tea" is merely a generic term for an extremely broad class of at least several hundred plant varieties, all deriving from the *Camellia sinensis* plant. Moreover, as Applicants have previously argued, all green teas are not created equal, at least with respect to the catechol and caffeine content. The Declaration of Max Rombi, submitted herewith, contains data, previously submitted in the

Response filed April 2, 2002 (see pp. 7-8 of the Response), pertaining to the catechol and caffeine content of different types of green tea and with different extraction solvents. As discussed in Paragraph 9 of the Declaration, several green teas were subjected to the exact same extraction with 80% ethanol, yet not every green tea produces the proportions and amounts of catechols and caffeine shown to be efficacious in the presently claimed invention. To meet the limitations of the claims, a green tea extract must contain from 20% to 50% by mass of catechols and from 5% to 10% of caffeine. As seen from Table 1 in the Declaration, it is not necessarily so that a particular green tea variety meets the necessary claim limitations when using an 80% ethanol extract. Therefore, contrary to the Examiner's statement, it continues to be, and has been, the Applicant's position that it is **not** "**inherent**" that an 80% ethanol (or any other extraction solvent, for that matter) extract possesses the particular proportion and amounts of catechols and caffeine required by the present claims.

Mr. Rombi's Declaration further demonstrates that varying the content of the extraction solvent itself influences the proportion and amounts of catechols and green tea. Paragraph 10 of the declaration shows the variation in content that arises, with the same green tea, with different extraction solvents. Thus, even varying the extraction solvent has an important impact on whether an extract that meets the present claim limitations is obtained.

The Examiner has provided no evidence that the green tea of Yasuda, beyond the use of an 80% ethanol extraction, possesses the quantities and proportions required by the presently claimed invention. Applicants have demonstrated above that the 80% ethanol

extraction is not a sufficient or accurate indicator of whether the green tea extract of Yasuda contains 20-50% by mass of catechols and 5-10% of caffeine. Yasuda has given no indication of such content. In fact, upon extracting the green tea with 80% ethanol, the extract is not analyzed at all, but rather is immediately chromatographed to obtain fractions containing particular tea catechins. Yasuda adds these separately fractionated catechins to chewing gum to determine the effect on halitosis, an effect so remote from the presently claimed invention so as to be completely unrelated. The proportion and amount of caffeine, an essential element of the synergistic combination, is not even mentioned in Yasuda.

Thus, in light of Applicant's data regarding the variability in the catechol and caffeine content even with a particular extraction solvent, the failure of Yasuda to indicate the particular type of green tea used, and the lack of any analysis by Yasuda on the green tea extract itself, there is nothing in the Yasuda publication that is of use to the Examiner in concluding that the present claims are anticipated.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of anticipation based on the Yasuda publication. Withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 5, 16, and 26-28 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Yasuda et al. The Examiner acknowledges that Yasuda et al. do not disclose the particular milligram amounts of EGCG and caffeine. However, the Examiner argues that the ordinary artisan would have recognized that the claimed amounts of EGCG and caffeine

were all within the ratio obtained in a 80% ethanol green tea extract. The Examiner also notes that the skilled artisan would have been motivated to have extracted green tea on a large scale. This rejection is respectfully traversed.

Applicants respectfully submit that the remarks made above under the 35 U.S.C. § 102(b) rejection are equally applicable to the rejection under 35 U.S.C. § 103(a).

Applicants do not believe the Examiner's comments concerning motivation to produce the claimed invention on a large scale to be relevant as claims 5, 16, 27, and 28 are drawn to particular amounts of extract for a daily dosage. It is not clear to Applicants how the discussion of large scale extraction is relevant. Clarification of this issue is respectfully requested.

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See M.P.E.P. §2142.

The Examiner has previously noted that a *prima facie* case of obviousness can be rebutted by a showing that the prior art products do not necessarily possess the characteristics of the claimed product. Office Action mailed November 2, 2001 (Paper No. 12), page 6, citing *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). Applicants have demonstrated above the failure of Yasuda et al. to disclose the particular proportions and amounts of catechols and caffeine (which is not discussed at all) of the presently claimed invention and the fact that a particular catechol and caffeine content is not inherent in a particular extract. Additionally, the rejected claims recite specific amounts of catechols in

proportion to caffeine. Yasuda et al. do not mention caffeine and the amounts of catechins discussed by Yasuda do not fall within the claim limitations. Accordingly, the Yasuda et al. publication does not disclose or suggest all of the claim limitations.

Further, Yasuda et al. provide no motivation for obtaining the presently claimed invention. As noted above, Yasuda et al. were concerned with determining the effect of various tea catechins on combating bad breath. Yasuda does not mention any proportions of catechins as being efficacious for the purposes of fighting halitosis. Nowhere in the Yasuda publication is there any mention of caffeine, which is a critical part of the presently claimed invention, or any indication that a particular proportion of caffeine and catechols would be synergistic in helping to maintain a desired weight or to treat obesity. Yasuda et al. does not even utilize the green tea extract itself, but rather continues to further isolate the various catechin components. Thus, one skilled in the art would not find motivation or guidance in the Yasuda et al. publication to arrive at the presently claimed invention.

The presently claimed invention is also nonobvious as evidenced by the commercial success discussed in the Declaration of Max Rombi. As can be seen from Paragraph 12 of the Declaration and the accompanying Exhibit 1, the novel green tea extract, AR-25, as described in the specification, is experiencing commercial success. From the period of August 28, 2002 to November 12, 2002, more than 17,360 kg of AR-25 totaling \$677,040 were sold. Moreover, estimates from the distributor marketing AR-25 total 40,000 kg for the first quarter of 2003. The impressive commercial success of AR-25, a green tea extract according to the presently claimed invention, demonstrates that the presently claimed invention is not obvious.

Thus, a *prima facie* case of obviousness based on Yasuda et al. has not been established for failure to disclose or suggest all of the claimed elements and to provide motivation to arrive at the presently claimed invention. Additionally, the presently claimed invention is supported by evidence of commercial success, which is a further indication of nonobviousness. Accordingly, withdrawal of this rejection is respectfully requested.

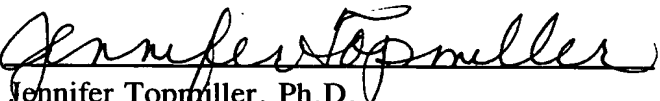
Conclusions

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Jennifer Topmiller, Ph.D.
Registration No. 50,435

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

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